



September 15, 2016

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Re: Initial Evaluation of the Amended TSCA Confidentiality Provisions

Dear Barbara:

On behalf of the American Chemistry Counsel (ACC), I thought it would be useful to share with EPA ACC's initial ideas on how the various provisions of the amendments made to the Toxic Substances Control Act (TSCA) by the Lautenberg Chemical Safety Act (LCSA) should be interpreted. We would appreciate the opportunity to hear EPA's ideas as well and to discuss both perspectives. I look forward to our discussion on these provisions in the near future.

SUMMARY

This letter provides ACC's initial views about some of the key aspects of amended section 14 as they relate to confidential chemical identities. In summary:

- The LCSA amendments to section 14 essentially continue the statutory approach to protection of confidential chemical identities from disclosure embodied in the original TSCA.
- Section 14(a) is a reverse-FOIA provision which prohibits EPA from disclosing confidential business information (CBI) exempt from mandatory disclosure under exemption (b)(4) of the Freedom of Information Act (FOIA), except as provided elsewhere in section 14.
- Section 14(b) identifies limited exclusions from section 14(a). These exclusions continue to allow CBI claims for confidential chemical identities, even if contained within health and safety studies that must otherwise be disclosed.
- FOIA mandates disclosure; TSCA does not. To the extent that information excluded by section 14(b) is also exempt from mandatory disclosure under FOIA exemption (b)(4), EPA has discretion to disclose or withhold that information. EPA should continue to



balance the competing interests of public access to the CBI in health and safety studies and protection of trade secrets contained in those studies. Where a structurally descriptive generic name is provided, as is now mandated by section 14(c)(1)(C), disclosure of the specific chemical identity is not necessary. Thus, wherever structurally descriptive generic names are provided, EPA should not disclose confidential chemical identities covered by section 14(b).

- Section 14(g)(4) directs EPA to establish a unique identifier for each specific chemical identity for which it approves a request for protection from disclosure. EPA should not assign unique identifiers in a manner that reveals confidential chemical identities.

DISCUSSION

1. The LSCA Made Few Changes Relating to the Confidential Status of Chemical Identities Claimed as CBI

The amendments to section 14 did not affect the basic issue of whether confidential chemical identities must be protected from disclosure or must be disclosed. Instead, they primarily addressed the processes information submitters will follow when requesting protection from disclosure of CBI, and that EPA will use when evaluating those claims. Nothing in the legislative history of the LCSA suggests a congressional intent to alter the previous provisions as they relate to disclosure or protection of confidential chemical identities in health and safety studies submitted under TSCA.¹

Before the recent amendments, section 14(b) did not apply to CBI in health and safety studies that would reveal process information and that continues to be the case. However, an amendment clarified that among the process information that is excluded from section 14(b) (and which therefore is protected by section 14(a)) is “formulas (including molecular structures) of a chemical substance or mixture.” The term “molecular structures” is a way of referring to chemical identities.² Thus, amended section 14(b) expressly protects confidential chemical identities from disclosure when the identities would reveal process information. This express protection does not imply, however, that confidential chemical identities that would not reveal process information are subject to section 14(b). EPA retains the discretion to protect confidential chemical identities in other circumstances.

In light of the small substantive change to section 14(b), most aspects of the attached 2012 ACC White Paper, “TSCA Protects Confidential Chemical Identities in Health and Safety Studies from Disclosure,” (White Paper) remain relevant.³ The White Paper reviews policy reasons why

¹ ACC acknowledges one exception to this point – namely the clear mandate to disclose what had been protected as CBI when CBI protections are withdrawn or cannot be maintained.

² Section 10(b) of FIFRA, which protects trade secrets from disclosure, similarly specifies that “formulas of products” may not be disclosed, even though health and safety studies must otherwise be disclosed. That provision has long been understood as precluding EPA from disclosing the confidential chemical identities of inerts in a pesticide formulation, even if mentioned in a health and safety study.

³ ACC submitted the White Paper to EPA on January 20, 2012, and discussed it with Assistant Administrator Jim Jones and his staff in a meeting on February 14, 2012.

EPA should protect confidential chemical identities from disclosure;⁴ interprets statutory provisions throughout TSCA that protect such identities from disclosure;⁵ shows how the legislative history of section 14(b) supports protection of confidential chemical identities; and reviews EPA's practices throughout its implementation of TSCA to protect those identities.

The White Paper recommends that EPA require up-front substantiation of CBI claims for confidential chemical identities and disclosure of structurally descriptive generic names for such identities. The amendments to section 14 effectively implement both of those recommendations.

2. Section 14(a) Prohibits Disclosure of CBI Not Subject to an Exception

It is helpful to recognize section 14(a) as a reverse-FOIA provision that prohibits disclosure of information exempt from mandatory disclosure under FOIA, except to the extent that other provisions of section 14 (such as section 14(b)) create exceptions to that prohibition. Congress enacted this and other reverse-FOIA provisions because "FOIA is exclusively a disclosure statute" and "does not give the authority to bar disclosure" because "Congress did not design the FOIA exemptions to be mandatory bars to disclosure."⁶ The point of a reverse-FOIA provision is to prohibit disclosure. Section 14(a) has counterparts in other federal regulatory statutes.⁷

Accordingly, section 14(a) establishes the basic approach for deciding whether to protect confidential chemical identities from disclosure. That protection is mandatory except to the extent that an exception applies. This means that the exceptions should be read narrowly.

3. Under Section 14(b), Confidential Chemical Identities in Health and Safety Studies Are Protected from Disclosure

The LCSA made only minor changes to the exceptions in section 14(b) from the protection from disclosure provided by section 14(a). The meaning of those exceptions essentially has not changed.

In 2010, EPA announced its interpretations of the section 14(b) exceptions.⁸ Generally, those interpretations indicated that EPA would not protect from disclosure chemical identities on the public Inventory (unless the identities revealed process or percentage of mixture information). In response, ACC submitted to EPA the attached White Paper disagreeing with certain EPA interpretations and policy changes. In particular, the White Paper maintained that under section 14(b)(1), health and safety effects information in studies submitted under TSCA is not protected from disclosure, but confidential chemical identities (whether or not on the confidential Inventory) in those studies are protected from disclosure.

⁴ One of those policy reasons was protection of trade secrets because of the economic value that they bring to the U.S. That reason was reiterated by the recent enactment of the Defend Trade Secrets Act of 2016, Pub. L. 114-153 (May 11, 2016) only a few weeks before enactment of the LCSA.

⁵ In some cases, the LCSA revised the subsections in which those provisions appear, but most or all remain in TSCA as amended.

⁶ *Chrysler Corp. v. Brown*, 441 U.S. 281, 285, 293-294 (1979).

⁷ E.g., Consumer Product Safety Act § 6(a)(2), 15 U.S.C. § 2055(a)(2).

⁸ 75 Fed. Reg. 3462 (Jan. 21, 2010) (confidential chemical identities submitted under section 8(e)); 75 Fed. Reg. 29754 (May 27, 2010) (confidential chemical identities in health and safety studies).

The legislative history of the LCSA's amendments to section 14(b) apparently referred to this debate:

[The Senate Committee bill] retains virtually verbatim the language of existing section 14(b)(1), relating to the disclosure of confidential information in the context of a health and safety study. The adoption of this provision of existing law does not signal the Committee's intent to agree or disagree with EPA's interpretation of the provision to date. Rather, it reflects the significant debate over the scope and interpretation of that provision, which could not be successfully resolved.⁹

However, Congress did enact new language relating to CBI contained in a health and safety study, new section 14(b)(1), which provides:

MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—
Information that is protected from disclosure under this section, and which is mixed with information that is not protected from disclosure under this section, does not lose its protection from disclosure notwithstanding that it is mixed with information that is not protected from disclosure.

The Senate Committee Report commented on an earlier version of that language, stating:

The Committee expects that EPA will ensure that health and environmental effects information from health and safety studies is disclosed, while appropriately protecting CBI contained within a study.¹⁰

The House Committee Report made the same point:

Fifth, the legislation clarifies that while health and safety studies about a specific chemical substance or mixture are not eligible for protection as CBI, those studies cannot reveal data that would disclose formulas, including molecular structures, for chemical substances and mixtures whose protection as confidential has been justified to EPA. The Committee expects that redactions or the use of approved generic names or unique identifiers will be employed to meaningfully inform the public without comprising trade secrets.¹¹

This position is similar to that espoused by the EPA General Counsel in 1976, who opined that the 1972 version of FIFRA mandated the disclosure of effects information in health and safety studies submitted under FIFRA, but protected from disclosure "confidential ingredient

⁹ S. Rep. 114-67 (June 18, 2015) at 22, <https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf>.

¹⁰ Id.

¹¹ H.R. Rep. 114-176 (June 23, 2015) at 30, <https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf>.

statements” in those studies.¹² Other environmental statutes also require disclosure of effects information but protect confidential chemical identities from disclosure.¹³

With this clarification in new section 14(b)(1), Congress clearly contemplated that not everything in a health and safety study is to be disclosed if it would otherwise be protected by section 14(a). It strongly suggests that confidential chemical identities otherwise protected by section 14(a) must be protected from disclosure.

In short, section 14 protects confidential chemical identities in health and safety studies submitted under TSCA, even if those identities are on the public TSCA Inventory.

4. Section 14(b) Does Not Mandate Disclosure of Health and Safety Studies

Amended section 14(b)(2) does not mandate disclosure of health and safety studies submitted under TSCA; instead, it provides simply that “Subsection (a) does not prohibit the disclosure of” certain health and safety studies and other specified information. FOIA does not mandate disclosure of such CBI either, due to exemption (b)(4). Because CBI in health and safety studies subject to section 14(b)(2) is neither protected from disclosure nor subject to mandatory disclosure, EPA must exercise its discretion in deciding whether or not to disclose such CBI.

Historically, EPA has exercised that discretion by balancing the competing interests of disclosure and protection against loss of trade secrets. In the context of health and safety studies submitted with PMNs, EPA has concluded that it will not protect confidential chemical identities from disclosure *unless* “[t]he specific chemical identity is not necessary to interpret a health and safety study.”¹⁴ Where the specific chemical identity is unnecessary for that purpose, it will protect the CBI. When adopting this position, EPA explained:

In an attempt to meet both these concerns, EPA has chosen an approach that balances the need for confidentiality, the need to understand health and safety studies, and the provisions of TSCA...

Under § 720.90(c) of the rule, if any health and safety studies have been submitted for the chemical substance in question, the specific chemical identity will be held confidential only if disclosure would reveal confidential manufacturing or processing processes or the confidential proportions of substances in a mixture, or if the specific chemical identity is not necessary to interpret any of the studies ...

Companies that claim specific chemical identity confidential in their notices who wish to argue that knowledge of the specific identity is not necessary to interpret their health and safety studies are encouraged to choose generic names which are sufficiently specific to interpret their health and safety studies. **Sufficiently specific generic names will tend to**

¹² Opinion No. 76-8 (Mar. 5, 1976), 1976 WL 25230 (E.P.A.G.C.), quoted in the White Paper at p. 17.

¹³ See the White Paper at pp. 23-26; Resource Conservation and Recovery Act of 1976, Pub. L. 94-580 (Oct. 21, 1976), § 3007(b) (enacted 10 days after TSCA).

¹⁴ 40 C.F.R. § 720.90(c).

support arguments that disclosure of the specific chemical identity is not necessary to understand the study.¹⁵

As amended by the LCSA, section 14(c)(1)(C) now mandates that any claim for protection of confidential chemical identities must include “a structurally descriptive generic name.” With this new requirement, the balancing of interests should always favor protection of the CBI.

5. EPA Should Not Implement the Unique Identifier Provision to Reveal CBI

New section 14(g)(4) directs EPA to assign a unique identifier to any confidential chemical identity which it withholds from disclosure. This identifier must be unique, in contrast to a structurally descriptive generic name, which can apply to multiple chemical substances having a similar molecular structure. The purpose behind this provision is to provide an easy way of identifying all related CBI information that would be disclosed when a claim is withdrawn, denied, or when the criteria for protection are not met. However, the unique identifier must be applied very carefully so as not to inadvertently disclose confidential information. EPA must take care to protect links to company identities and information on commercialization when that information is claimed confidential.

Where the confidential chemical identity is already on the confidential Inventory, the accession number could serve as the unique identifier. There are no accession numbers for chemicals that are not on the Inventory, however, so accession numbers must only be one source among others for unique identifiers.

For example, many R&D chemicals are not on the TSCA Inventory. A PMN submitter must submit all health and safety studies on the PMN substance as part of the PMN, at which time the PMN substance does not have an accession number (and EPA would assign an accession number only if subsequent to the end of the PMN review period the PMN submitter were to submit a notice of commencement). In addition, chemicals being evaluated for their potential to be used as pesticides (subject to TSCA prior to application of FIFRA¹⁶) are typically not on the Inventory, and yet they may be the subject of submissions under section 8(e). If those pesticide candidates are successful, they would become subject to FIFRA and would never receive an accession number. For these chemicals, EPA would either have to assign a unique identifier other than an accession number, or delay assigning a unique identifier until such time, if ever, that it does assign an accession number.

¹⁵ 48 Fed. Reg. 21722, 21739-40 (May 13, 1983) (emphasis added). This resolution parallels the legislative history of section 5(d)(2), which directs EPA to identify PMN chemicals in Federal Register notices “by generic class” unless a more specific identification is required in the public interest. The Senate Report for an early TSCA bill with a provision which became section 5(d)(2) in a later bill explained that such a generic name, “coupled with the test results that are made available would be valuable to independent scientists who have knowledge of similar chemical substances and the toxicity characteristics that might be expected of a member of that same family. If the test results published vary significantly from the known toxicity of similar substances, then the independent scientist could have good reason to question the published results.” S. Rep. No. 97-283 at 20 (1972). In other words, Congress contemplated that having a structurally descriptive generic name would enable the public to understand a study without the need to disclose confidential chemical identities revealed in the studies.

¹⁶ See 40 C.F.R. § 720.36(g).

In addition, as discussed in section 3 of this letter, a confidential chemical identity may be on the public Inventory. These chemicals will not have accession numbers either. Thus, EPA will have to derive unique identifiers for these chemicals as well.

Where EPA has agreed to protect from disclosure a confidential chemical identity that is on the public Inventory, it should not use the unique identifier to reveal that identity by applying it to public information that specifically identifies that chemical. For example, if it is a trade secret that chemical X (which is on the public Inventory) is in a formulated product that is the subject of study submitted to EPA under TSCA, and EPA has agreed to keep the identity of chemical X confidential with respect to that study, EPA should not apply the unique identifier to other public information that gives the specific chemical identity of chemical X. That would reveal the very information that EPA had agreed to keep confidential.

CONCLUSION

I look forward to discussing the paper with you and your staff.

Sincerely,

A handwritten signature in blue ink that reads "Christina Franz". The signature is written in a cursive, flowing style.

Christina Franz
Senior Director, Regulatory & Technical Affairs

Enclosure: ACC White Paper, "TSCA Protects Confidential Identities in Health and Safety Studies From Disclosure" (Feb. 21, 2012)